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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/660,601 | 09/12/2003 | R. Donald Grafton | A8130.0153/P153 | 7642 |
| 24998 | 7590 | 11/21/2007 | | |
| DICKSTEIN SHAPIRO LLP 1825 EYE STREET NW Washington, DC 20006-5403 | | | EXAMINER RYCKMAN, MELISSA K | |
| | | | ART UNIT 3773 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/660,601 | Applicant(s) GRAFTON ET AL. | |
| | Examiner Melissa Ryckman | Art Unit 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on claims received on 8/30/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to claims and arguments filed 8/30/07.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 3, 7-9, 11, 12, 15, 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins, Jr. (US 5571139) in view of Grafton et al. (US 5964783).

Jenkins Jr. teaches a suture anchor (1) comprising:

- a bioabsorbable (Column 3, proximate line 42) anchor body (13) having a proximal end and a distal end; and a suture eyelet (27 or 28) formed of a strand of suture (it is noted that knot 27 comprises a suture eyelet), the suture eyelet being disposed completely within the anchor body.

- wherein the suture anchor has a predetermined length and wherein the suture eyelet (28) is recessed from the proximal end of the anchor body by about one third of the predetermined length (fig. 3b)
- wherein the anchor body is provided with a drive socket (31) and the suture eyelet is disposed within the drive socket (fig. 3b)
- comprising a strand of a knot tying suture threaded through the suture eyelet (it is noted that the non-loop portion of the knot 27 or 28 is a strand of knot tying suture)
- wherein the anchor body is treaded from the proximal end to the distal end (fig. 1)
- wherein the anchor body has a constant outer diameter and a tapered inner diameter (fig. 2)
- the suture loop is a suture eyelet (28, when the loop is formed, there is an eyelet for the suture to pass through)

Jenkins Jr. fails to teach wherein the suture eyelet is insert-molded into the anchor body. Grafton teaches a suture anchor wherein a suture material is insert molded into the anchor body in order to increase pull out strength of the suture from the anchor body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Jenkins Jr. with an insert-molded suture loop in order to increase pull out strength of the suture from the anchor body.

Claims 10, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Jenkins Jr. and Grafton (5964783) and further in view of Grafton et al. (US 6319270).

The combination of Jenkins Jr. and Grafton (5964783) teaches all limitations of previous dependent claims 1, 9, 11, and 17 as previously described, but fails to teach wherein the anchor body has a constant outer diameter and a stepped tapered inner diameter and wherein the anchor thread extending between the proximal end and the distal end of the body has a crest which tapers from wide to narrow from the proximal end to the distal end of the body.

Grafton (6319270) teaches a suture anchor wherein the anchor body has a constant outer diameter and a stepped tapered inner diameter and wherein the anchor thread extending between the proximal end and the distal end of the body has a crest which tapers from wide to narrow from the proximal end to the distal end of the body in order to provide an increased percentage of thread surface area for each turn of the anchor, thus providing increased pull-out strength, and a decreased tendency for back-out (Column 2, proximate lines 1-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Jenkins Jr. and Grafton (5964783) as taught by Grafton (6319270) in order to provide an increased percentage of thread surface area for each turn of the anchor, thus providing increased pull-out strength, and a decreased tendency for back-out.

Claims 4 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Jenkins Jr. and Grafton (5964783) as previously described, and further in view of Jackson (US 6454772).

The combination of Jenkins Jr. and Grafton (5964783) teaches all limitations of preceding dependent claims 1 and 11, but fails to teach wherein the drive socket has at least one slot for receiving a corresponding protrusion on a driver head. Jackson teaches a threaded surgical implant, comprising a drive socket having a pair of slot tool receivers in order to receive a corresponding protrusion on a driving tool for effective delivery of the device to the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Jenkins Jr. and Grafton (5964783) with slot tool receivers as taught by Jackson in order to receive a corresponding protrusion on a driving tool for effective delivery of the device to the tissue.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dreyfuss (6652563), and further in view of Grafton (5964783).

Dreyfuss teaches a suture anchor (6) comprising an anchor body (6) having a proximal end, a distal end, and a drive socket (132, Figs. 3 and 6) at the proximal end; a suture loop (122), the suture loop being completely within the anchor body (Fig. 5), wherein the drive socket has at least one slot (Fig. 3) for receiving a corresponding protrusion on a driver head for driving the suture anchor (Fig. 6), wherein the slot terminates distally in a suture hole (where 138 meets 122) provided within the anchor

body (slot 132 terminates distal of 122 Fig. 5), the suture hole (where 138 meets 122) is transverse to a longitudinal axis of the anchor body (Fig. 5).

Dreyfuss does not teach a bioabsorbable anchor body or the suture eyelet is insert-molded into the anchor body. Grafton teaches a bioabsorbable (col. 3, ll. 36) suture anchor wherein a suture material is insert molded into the anchor body in order to increase pull out strength of the suture from the anchor body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Dreyfuss with a bioabsorbable material, a bioabsorbable material is helpful because the suture anchor may not be needed permanently and removal of the anchor is unnecessary. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Dreyfuss with the anchor being bioabsorbable an insert-molded suture loop in order to increase pull out strength of the suture from the anchor body.

Response to Arguments

Applicant's arguments filed 8/30/07 have been fully considered but they are not persuasive. The applicant generally argues the following:

- Jenkins teaches two suture knots and not a "suture eyelet"
- Grafton does not have a bioabsorbable anchor body

The examiner respectfully disagrees with the applicant, Jenkins teaches a suture eyelet as stated above, when the loop 28 is formed, there is an eyelet for the suture to

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pass through. Grafton '783 teaches a bioabsorbable (col. 3, ll. 36) suture anchor as stated above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

A handwritten signature in black ink, appearing to read "M. J. Hayes", written in a cursive style.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER